



DEPARTMENT OF HEALTH AND HUMAN SERVICE

54437d
Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
FAX: 504-253-4520

December 12, 2003

WARNING LETTER NO. 2004-NOL-08

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Floyd L. Poche, President/Owner
Floyd Poche Enterprises, Inc.
d.b.a. Poche's Market & Restaurant
d.b.a. Poche's Smokehouse
3015 Main Highway (Highway 31)
Breaux Bridge, Louisiana 70517

Dear Mr. Poche:

The U.S. Food and Drug Administration (FDA) inspected your food manufacturing and distribution facility located at 3015 Main Highway (Highway 31), Breaux Bridge, Louisiana, on August 11 – 14 and 27 – 29, 2003. During the inspection, labeling and product formulation sheets were collected for several of your products, including Poche's Crawfish Boudin, Poche's Pecan Pie, Poche's Sweet Dough Pies, Tony's Seafood Pecan Praline, and Poche's Barbecue Sauce. Review of the labels for these products found that the products are misbranded within the meaning of Section 403(q)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the labels fail to bear nutrition information as required by 21 *Code of Federal Regulations* (CFR) 101.9, and the products are not exempt from this requirement under Section 403(q)(5). You can find the Act and the implementing regulations through links in FDA's home page at www.fda.gov.

The above-named products also are misbranded within the meaning of Section 403(i)(2) of the Act because they are formulated with products that contain two or more ingredients, but the labels fail to bear the common or usual name of each of the ingredients in these products as required by 21 CFR 101.4(b)(2). For example, Poche's Crawfish Boudin contains Cream of Mushroom soup, dried dairy blend, margarine and crawfish base; however, the ingredient statement does not include the components of each of these ingredients. In addition, the ingredient statement for Poche's Barbecue Sauce fails to identify the ingredients used in Worcestershire Sauce and margarine. The requirement to list the component ingredients may be met by either parenthetically listing the component ingredients after the common or usual name of the main ingredient, or by listing the component ingredients without listing the ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance in the main ingredient; and, under the second alternative, the component

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ingredients must be listed in descending order of predominance in the finished food [21 CFR 101.4(a)(1) and 101.4(b)(2)].

According to the product formulation sheets collected during our August 2003 inspection, undeclared component ingredients in your products include wheat flour, milk, and soy, which are known allergens. Undeclared ingredients that are known allergens are of particular concern to FDA. The FDA has received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic reactions are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products.


In addition, the Poche's Pecan Pie, Poche's Sweet Dough Pies, and Tony's Seafood Pecan Praline are misbranded within the meaning of Section 403(e)(1) of the Act because the labels fail to identify the place of business of the manufacturer, packer or distributor as required by 21 CFR 101.5(d).

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. Such actions may include initiation of seizure, injunction, or prosecution actions in Federal court.

You should notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, along with a copy of the revised labels. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Cynthia R. Crocker, Compliance Officer, U.S. Food and Drug Administration, 100 W. Capitol Street, Suite 340, Jackson, Mississippi 39269. Should you have any questions regarding the contents of this letter, please contact Ms. Crocker at (601) 965-4581, ext. 106.

Sincerely,


Patricia K. Schafer
Acting District Director
New Orleans District